

Amendments to the Drawings:

The attached sheet of drawings includes changes to Fig. 3. This sheet, which includes Fig. 3, replaces the original sheet including Fig. 3. In Figure 3, the line pointing to the drawing that was not labeled with a reference number has been removed. In addition, formalized versions of the remaining figures, e.g. 1-2, 4-8, are attached for approval by the Examiner.

Attachment: Replacement Sheets

Annotated Sheets Showing Changes

Remarks/Argument

Claims 1-4 and 6-23 remain in this application.

Claim 5 has been canceled.

Claim 24 has been added.

Claim 24 adds an additional feature from the figures as well as the specification.

In response to the Office Action of December 31, 2003, Applicant requests re-examination and reconsideration of this application for patent pursuant to 35 U.S.C. 132.

Objections to the Claims

Claim 5 stands objected to because the term "tensioer" should be changed to "tensioner".

Claim 5 has been cancelled and thus this objection is moot.

Claim 7 stands objected to because the term "ins" should be changed to "in".

Claim 7 has been amended to correct the typographical error and thus the Applicant requests that this objection be removed.

Rejections under 35 USC 112

Claims 11 and 20 stand rejected under 35 USC 112, second paragraph, as being indefinite.

With regard to claim 11, the Examiner states that it is unclear whether the "slot connected to said bore" is positioned in the provisional clamp or the permanent clamp.

Claim 11 has been amended to clarify that the slot is connected to the provisional clamp bore and thus the Applicant requests that this rejection be removed.

With regard to claim 20, the Examiner states that the term "with said bore aligned" is unclear. The Examiner also points out that there is insufficient antecedent basis for the terms "said aperture" and "said working end".

Claim 20 has been amended to clarify that the bore of the provisional clamp is aligned with the cable bore.

Claim 20 has also been amended from "said aperture" to "cable bore" to provide proper antecedent basis for the terms used therein.

Claim 20 has also been amended from "said working end" to "said shaft end" to provide proper antecedent basis for the terms used therein.

Rejections under 35 USC 102(b)

Claims 6-8 stand rejected under 35 USC 102(b) as being anticipated by Golds et al. US 5,356,412. The Examiner's position

is respectfully traversed.

Golds discloses a sternum buckle with rotational engagement and method of closure. The Golds device includes a clamp body having at least one aperture therethrough for passage of a cloth ribbon. Inside of the clamp body is a rotationally mounted "clamp" which only allows the ribbon to be moved in one direction. The device does not provide for loosening of the ribbon requiring the ribbon to be cut and reinserted should the ribbon be over-tightened. The Examiner states that Golds discloses a provisional clamp which cooperates with the permanent clamp of Golds to permit advancement of the ribbon while preventing retrograde thereof. The Applicant can find no such device depicted or described in the Golds reference.

In contrast, the permanent clamp of the instant invention, as amended, includes a "manually actuated stop" which allows the cable to moved in either direction while in a first position and prevents movement of the cable in either direction while in a second position. The stop be operated by a substantially linear motion as depicted in the Figs. Because the permanent clamp of the instant invention permits the cable to move in either direction prior to engagement of the stop the provisional clamp provides a one way clutch mechanism for maintaining the tension on the cable until the

stop is actuated. The provisional clamp also includes a release which allows a surgeon to release the cable at any time prior to or subsequent to engagement of the stop. Golds does not provide any mechanism that can be utilized to release the strap used to hold the tissue together.

It is well established that in order for a claim to be anticipated each and every element as set forth in the claim must be found, either expressly or inherently described in a single prior art reference (see MPEP 2131). Thus, it is respectfully submitted that the structural limitations of the instant invention distinguish over the prior art of record and the Applicant requests that this rejection be removed and the claims be allowed to issue.

Rejection under 35 USC 103(a)

Claims 9-11 stand rejected as unpatentable over Golds et al US 5,356,412. The Examiner's position is respectfully traversed.

As discussed above, Golds discloses a sternum buckle with **rotational engagement** and method of closure. The Golds device includes a clamp body having at least one aperture therethrough for passage of a cloth ribbon. Inside of the clamp body is a **rotationally** mounted "clamp" which only allows the ribbon to be moved in one direction. The device does not provide for loosening

of the ribbon, requiring the ribbon to be cut and reinserted should the ribbon be over-tightened or for removal of the device from the patient. The Examiner states that Golds discloses a provisional clamp which cooperates with the permanent clamp of Golds to permit advancement of the ribbon while preventing retrograde thereof. The Applicant can find no such device depicted or described in the Golds reference.

In contrast, the permanent clamp of the instant invention, as amended, includes a "manually actuated stop" which **allows the cable to moved in either direction** while in a first position and prevents movement of the cable in either direction while in a second position. The stop is operated by a substantially linear motion as depicted in the Figures and as described in the specification. **Because the permanent clamp of the instant invention permits the cable to move in either direction prior to engagement of the stop** the provisional clamp provides a one way clutch mechanism for maintaining the tension on the cable until the stop is actuated to prevent motion of the cable in either direction. The provisional clamp also includes a release which allows a surgeon to release the cable at any time prior to or subsequent to engagement of the stop. Golds does not provide any mechanism that can be utilized to release the strap used to hold the tissue together requiring the

strap to be cut for removal or loosening.

It is well settled that a showing of obviousness requires a motivation or suggestion to combine or modify prior art reference, coupled with a reasonable expectation of success, See *Brown & Williamson Tobacco Corp. V. Philip Morris Inc.*, 229 F.3d 1120, 1124-25, 56 USPQ2d 1456, 1459 (Fed. Cir 2000). Because the device of Golds is structurally and functionally different than the instant invention which provides the capability of moving the cable in both directions prior to engagement of the stop the Applicant asserts that the Golds reference could not obviate the instant invention. Therefore, because Golds does not show or suggest a clamp that allows the cable to move in both directions prior to engagement of the stop, the Applicant requests that this rejection be removed and the claims, as amended, be allowed to issue.

With respect to claims 10 and 11 the Examiner states that it would have been obvious to construct the system of Golds with two clamps instead of one. The Examiner's position is respectfully traversed. For the reasons stated above the device of Golds operates and is constructed in a different manner than the instant invention. Moreover, the permanent clamp and the provisional clamp do not function and are not constructed in the same way. Therefore, the Examiner's suggestion that there is merely a

duplication of parts is erroneous.

It is well settled that a showing of obviousness requires a motivation or suggestion to combine or modify prior art reference, coupled with a reasonable expectation of success, See *Brown & Williamson Tobacco Corp. V. Philip Morris Inc.*, 229 F.3d 1120, 1124-25, 56 USPQ2d 1456, 1459 (Fed. Cir 2000). Gold's does not show or suggest a two clamp system wherein a provisional clamp maintains the desired amount of tension on a cable so that the stop of the permanent clamp can be engaged to lock the cable in position and thereafter the provisional clamp can be removed.

Claims 1-23 stand rejected as unpatentable over Golds et al US 5,356,412 in view of Cohen (US Pub 2002/0072753). The Examiner's position is respectfully traversed.

Cohen discloses a device that operates very closely to that of a caulking gun. The device includes a rack gear extending along the length thereof. A pawl secured to the trigger engages the rack gear in a racheting fashion. Strands of fiber are secured to the gear rack via threaded ends and a pair of rotatably mounted cams pinch the fibers against the side of the device to prevent loss of tension. The fibers of Cohen are tied in place. Like Golds, this construction would require the fibers to be cut for loosening or for removal. Cohen does not show or suggest any type of multi-

strand cable nor any type of permanent clamp secured to the cable.

Golds discloses a sternum buckle with **rotational engagement** and method of closure. The Golds device includes a clamp body having at least one aperture therethrough for passage of a cloth ribbon. Inside of the clamp body is a **rotationally** mounted "clamp" which only allows the ribbon to be moved in one direction. The device does not provide for loosening of the ribbon, requiring the ribbon to be cut and reinserted should the ribbon be over-tightened or for removal of the device from the patient. The Examiner states that Golds discloses a provisional clamp which cooperates with the permanent clamp of Golds to permit advancement of the ribbon while preventing retrograde thereof. The Applicant can find no such device depicted or described in the Golds reference. Because the clamp of Golds cannot be released to remove tension from the cable adding a second clamp to Golds would not serve any function. The only manner in which to loosen a ribbon with Golds is to cut the ribbon and start over. Adding a second clamp would only require the ribbon to be cut twice.

In contrast, the permanent clamp of the instant invention, as amended, includes a "manually actuated stop" which **allows the cable to moved in either direction** while in a first position and prevents movement of the cable in either direction while in a second

position. The stop is operated by a substantially linear motion as depicted in the Figures and as described in the specification. Because **the permanent clamp of the instant invention permits the cable to move in either direction prior to engagement of the stop** the provisional clamp provides a one way clutch mechanism for maintaining the tension on the cable until the stop is actuated to prevent motion of the cable in either direction. The provisional clamp also includes a release which allows a surgeon to release the cable at any time prior to or subsequent to engagement of the stop. Golds does not provide any mechanism that can be utilized to release the strap used to hold the tissue together requiring the strap to be cut for removal or loosening.

It is well settled that a showing of obviousness requires a motivation or suggestion to combine or modify prior art reference, coupled with a reasonable expectation of success, See *Brown & Williamson Tobacco Corp. V. Philip Morris Inc.*, 229 F.3d 1120, 1124-25, 56 USPQ2d 1456, 1459 (Fed. Cir 2000). Because the device of Golds is structurally and functionally different than the instant invention which provides the capability of moving the cable in both directions prior to engagement of the stop the Applicant asserts that the Golds reference could not obviate the instant invention. In addition, while the Cohen reference does show a

device which tensions fibers, the Cohen device is limited in range. That is the amount that the fiber can be tightened is limited by the length of the rack gear. Adding a longer rack gear adds weight and limits the usefulness of the tool. In contrast the tensioning device of the instant invention reciprocates pulling small amounts of cable at a time before returning to grab another bite of cable. The provisional clamp maintains the tension on the cable while the tensioning tool grabs another bite of cable. This allows a much smaller and more easily maneuverable tool for use in an operating room environment. Therefore, because Golds does not show or suggest a clamp that allows the cable to move in both directions prior to engagement of the stop and because Cohen does not show or suggest the use of a provisional clamp and a tensioner, the Applicant requests that this rejection be removed and the claims, as amended, be allowed to issue.

Summary

In light of the foregoing remarks and amendment to the claims, it is respectfully submitted that the Examiner will now find the claims of the application allowable. Favorable reconsideration of the application is courteously requested. Should there be any remaining issues which can be resolved via an Examiner's Amendment, the Examiner is urged to call the undersigned in order to expedite the prosecution of this application.

Respectfully submitted,

A handwritten signature in dark ink, appearing to read "Ferris H. Lander", is written over a horizontal line.

Ferris H. Lander
Registration # 43,377

McHale & Slavin, P.A.
2855 PGA Boulevard
Palm Beach Gardens, FL 33410
(561) 625-6575 (Voice)
(561) 625-6572 (Fax)